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Office of Extramural Research

Human Subjects System (HSS) (Grantees)

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CONTACT US

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DOCUMENT HISTORY

Date	System Version	Document Version	Description of Change	Author
June 21, 2018	1.0.0	1.0.0	Initial publication of document	eRA Communications
August 14, 2018	1.00.01	1.1.0	Updates to migrated IDR information for CT questions, warning on RPPR if CT indicated and no study is included, and new topic - "How To Change the Application Status and Resubmit".	eRA Communications
August 23, 2018	1.00.02	1.1.1	Added Additional Resources topic	eRA Communications

Date	System Version	Document Version	Description of Change	Author
September 13, 2018			<p><u>1 HSS Delegation</u></p> <p>Originally, only a Signing Official (SO) could submit HSS records to NIH. With this release of HSS, both the Progress Report delegation and the Submit delegation will be extended to HSS records.</p> <ul style="list-style-type: none"> • Progress Report Delegation <ul style="list-style-type: none"> ◦ Permits the contact Principal Investigator (PI) to delegate to a user with either the ASST (Assistant) or AO (Administrative Officer) role to work on a Progress Report, including HSS records. ◦ The SO, Account Administrator (AA), or AO can assign the Progress Report delegation to another PI named on the award, permitting them to work on a Progress Report, including HSS records. • Submit Delegation <ul style="list-style-type: none"> ◦ The Submit delegation can be assigned to the contact PI by the SO, permitting the 	eRA Communications

Date	System Version	Document Version	Description of Change	Author
			PI to submit all progress reports for Streamlined Non-competing Award Process (SNAP) awards. The PI is then listed as the Signing Official for that report. This functionality now includes the submission of HSS records.	
January 28, 2019			Updates have been made to the Edit Studies topic regarding Editing Inclusion Counts .	eRA Communications
March 29, 2019		1.2.0	Updates made to the Edit Studies topic to provide clarity on the two options available to access a study's edit screen.	eRA Communications

The most current version of this document will be available on the eRA intranet:

http://era.nih.gov/files/HSS_user_guide.pdf

TABLE OF CONTENTS

1 HSS Delegation	4
1 The Human Subjects System (HSS)	1
1.1 Purpose	1
1.2 Key Changes	1
1.3 How NIH grantees will use the system	2
1.4 Resources	2
2.1 Access Human Subjects System (HSS)	3
2.1.1 Human subjects information may need to be updated in the following scenarios:	3
2.0.0.1 Here is a quick summary of the ways HSS can be accessed (more detailed instructions follow):	3
2.1.2 To edit an existing study, log into eRA Commons and access the Human Subjects link via the RPPR or Status tabs.	4
2.0.0.2 Access via Status	4
SOs	4
PIs	6
Access via RPPR	8
3.1 Crosswalk Between IMS & HSS	10
4.1 Editing Studies	11
4.1.1 Human subjects information may need to be updated in the following scenarios: ...	11
4.1.2 To edit an existing study, log into eRA Commons and access the Human Subjects link via the RPPR or Status tabs.	11
4.0.0.1 Option 1	13
4.0.0.2 Option 2	14
4.1.3 Inclusion Enrollment Report	17
4.1.4 Editing Inclusion Counts	20
4.0.0.3 To use the template:	22

4.1.5 PI and SO Actions	24
5.1 Adding Studies	26
5.1 How To Change the Application Status and Resubmit	27
5.1.1 To revise and resubmit an application:	27
6.1 Convert Delayed Onset to Full Study Record	31
6.1.1 Flow:	31
7.1 Study Statuses	33
8.1 When Should I Access HSS via the Status Module?	34
8.1.1 When to Use the Status Module Instead of RPPR	34
8.1 Roles & Privileges	34
8.1.1 HSS ROLES & PRIVILEGES:	34
8.1 Additional Resources (HSCT form and more)	34

1 The Human Subjects System (HSS)

1.1 Purpose

The HSS system is a shared system that enables grant recipients to electronically report and update their data on human subjects and clinical trials to NIH; and for NIH agency staff to monitor and manage the data. HSS replaced the Inclusion Management System (IMS) and all IMS data submitted to NIH by June 8, 2018 was migrated to the new system.

The HSS is automatically populated by human subjects and clinical trial data entered by the principal investigator on the Human Subjects and Clinical Trial Information form in applications submitted for due dates of January 25, 2018 and beyond. This data is then made available to PIs and signing officials through a Human Subjects link that will be available on the eRA Commons Status screen and the Research Performance Progress Report (RPPR).

NOTE: HSS replaced the Inclusion Management System (IMS), used for reporting participant sex/gender, race, and ethnicity information. The Inclusion link no longer appears on the Commons Status page as of June 9, 2018.

1.2 Key Changes

1. NIH migrated enrollment records in IMS to HSS. *Updates to enrollment records must have been submitted to NIH no later than June 8, 2018 or entered in HSS.* Updates not submitted by June 8, 2018 are not available in HSS and must be re-entered.
2. NIH recipients completing an RPPR (Research Progress Performance Report) will be prompted to access HSS to update inclusion enrollment reports. Recipients may access the system through the Human Subjects link in the RPPR or the eRA Commons Status page.
3. *Section 6: Clinical Trial Milestone Plan* is intended for use in progress reports for competing applications submitted on or after January 25, 2018 and is not currently required unless otherwise noted in the Funding Opportunity Announcement or terms and conditions of award. Recipients should refer to the [RPPR Instruction Guide](#) for guidance.
4. The HSS system includes a new interface and workflow. When submitting studies to NIH, Signing Officials (or delegated contact PIs) will submit all study records associated with an application at one time rather than separately.
5. Participant-level sex/gender, race, ethnicity and age data may be submitted in a CSV file to populate the Inclusion Enrollment Report. Participant level data will be required for applications submitted January 25, 2019 or later. See [NOT-OD-116](#) for additional information.
6. Investigators and signing officials may make study updates or corrections (including just-in-time or off-cycle updates) by accessing HSS through the Human Subjects link in the eRA

Commons Status page. Some changes, including those involving increased risk to human participants, may require [prior approval](#) by NIH.

1.3 How NIH grantees will use the system

Depending on their roles and privileges, NIH grantees can use the Human Subjects system to:

- Edit existing studies
- Add studies
- Convert Delayed Onset studies

1.4 Resources

Additional resources such as video tutorials, crosswalk, and infographic on the Human Subjects System (HSS) are available at https://era.nih.gov/hss_training.htm.

Additional information about the PHS Human Subjects and Clinical Trials Information form is available at <https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm>.

2.1 Access Human Subjects System (HSS)

The *Human Subjects System* can be accessed by Principal Investigators (PIs) or Signing Officials (SOs) through either the RPPR or through the *Status* screen in eRA Commons

2.1.1 Human subjects information may need to be updated in the following scenarios:

- Post-award for updates to the Research Performance Progress Report (RPPR)
- Pre-award (post review) for just-in-time information or correction of human subjects data
- Off-cycle updates as required in the Funding Opportunity Announcement or terms and conditions of award
- Corrections to human subject data

2.0.0.1 Here is a quick summary of the ways HSS can be accessed (more detailed instructions follow):

- SO: Status tab > General Search screen > Specific Award > Action column > Human Subjects Link
- PI: Status tab > Status — PI Search screen > Status Result — List of Applications/Awards screen > Specific Award > Action column > Human Subjects Link
- Both: RPPR tab > Manage RPPR > Specific Grant > RPPR Menu screen > Edit button > Inclusion Section (G.4.b) > Human Subjects Link

Each method will result in access, via HSCT Post Submission, to inclusion enrollment reports in regular and delayed onset study records.

2.1.2 To edit an existing study, log into eRA Commons and access the Human Subjects link via the RPPR or Status tabs.

2.0.0.2 Access via Status

SOs

- SOs will now see a link on the *Status* page for **Pending Human Subjects Action**.

Status ?

Important Note:
Please provide additional search parameters to narrow down your searches promptly and avoid existing issue of delay in data retrieval.

→ [General Search](#)
[Just In Time](#)
[Pending Progress Report](#)
[Recently Awarded](#)
[Recent/Pending eSubmissions](#)
[Closeout](#)
[Change of Institution](#)
[Pending Human Subjects Action](#)
[Re-assign Award](#)
[Non-Research Continuations](#)
[ESI Eligibility](#)

Award Number	Type
Accession Number	
Grants.gov Tracking #	
PI Name	Last
Application Status	All
Eligible for FFATA Reporting	<input type="checkbox"/>

- Select the *Pending Human Subjects Action* link to be taken to the *Search for Applications* screen. On this screen, you may search via a submission status or use additional details to

narrow the search results.

Home > Search for Applications

Search for Applications ?

Application Identifier:

Application Project Title:

Agency:

PD/PI First Name:

PD/PI Middle Name:

PD/PI Last Name:

Lead Applicant Organization:

Submission Status: (select all that apply)

- Work in Progress
- All Components Final
- Ready for Submission
- Submitted
- Submission Errors
- Abandoned

Hide Abandoned Applications? ☒

HSS Applications? ☐

Submission Date: from to

Project Start Date:

Project End Date:

Search Clear

- On the resulting hitlist, click the **Select** button. The application summary page will be displayed.

Home > Search for Applications > Search for Application Results

Search for Application Results

1 - 4 of 4 records, Page 1 of 1

Application Identifier	Application Project Title	Agency	PD/PI Name	Lead Applicant Organization	Submission Status	Submission Date	Project Start Date	Project End Date	Action
21682	Registration for adaptive radiation therapy	NIH	Mouse, Fay	UNIVERSAL UNIVERSITY	Work in Progress		02/01/2013	01/31/2019	Select
22020	Social Isolation Among Older Adults	NIH	Thyme, Justin	UNIVERSAL UNIVERSITY	Work in Progress		01/15/2018	12/31/2019	Select
22102	Pathways Regulating Lung Transplant	NIH	Ermind, Nev	UNIVERSAL UNIVERSITY	Work in Progress		05/12/2015	04/30/2020	Select

- Additionally, the SO may use the *General Search* on the *Status* screen to produce a hitlist of

applications and then select the *Human Subjects* link in the *Action* column.

[Home](#)
[Admin](#)
[Institution Profile](#)
[Personal Profile](#)
Status
[ASSIST](#)
[Prior Approval](#)
[RPPR](#)
[xTrain](#)
[xTRACT](#)
[Admin Supp](#)
[eRA Partners](#)
[Non-Research](#)

Status Result - General Search ?

SO View

Tips and Notes:

- PD/PI column shows Contact PI for multi-PI grants.
- Modinat Test for April Release 2017

1- 100 of 442

12345

Application/Award ID	Grants.gov Tracking #	Proposal Title	PD/PI Name	Application Status	Budget Start Date	FFATA	Show All Prior Errors	Action
2R37DK123456-13		Mitigating KAOS Retrogressor effect	ADAMS, DON	Awarded. Non-fellowships only	05/01/2003			Human Subjects
2R37GM123456-26		STUDY OF RADIO WAVE IONISATION EFFECTS USING AGENT 99	FELDON, BARBARA	Awarded. Non-fellowships only	07/01/2005			
5R37DK000123-15		Ongoing Cone of Silence Diganostics	PLATT, EDWARD	Awarded. Non-fellowships only	08/01/2008			Closed Human Subjects
2R37AI000123-13		Acceptance of Credulity Statements Delivered in Decreasing Excessiveness	KOPELL, BERNIE	Awarded. Non-fellowships only	01/01/2006			
5R37DA999999-14		AGENT 86 AMNESIAAS MEANS TO PROTECT SCIENTISTS	KARVELAS, ROBERT	Awarded. Non-fellowships only	12/01/1999			Human Subjects
4R37GM123456-31		Probability Study Assessing Statistical Odds of Near Miss Projectiles	FRENCH, VICTOR	Awarded. Non-fellowships only	07/01/2010			

Export to Excel

Show Query

Print Hitlist

PIs

- A PI can click on the *Status* tab and then on *List of Applications/Awards* to see a list of their applications.

Home Admin Institution Profile Personal Profile **Status** ASSIST Prior Approval RPPR xTrain xTRACT Admin Supp eRA Partners

Non-Research

Status: PI Search

The Status screens have been updated. If you have any questions about the new Commons Status look and feel please contact the [eRA Service Desk](#).

The following list of applications represents a result of the search by Grants.gov Tracking # or a list of all Recent/Pending eSubmissions. If you do not see a complete list of your Recent/Pending eSubmissions, please click [Recent/Pending eSubmissions](#) menu tab again.

Recent/Pending eSubmissions

- Applications that require action (e.g., to view errors/warnings) prior to submission completion
- Applications that are available to view (during two business day correction window) prior to submission completion
- Applications that have been rejected by Signing Official

List of Applications/Awards

- Funded Awards
- Successfully submitted applications, both paper and electronic
- Review assignment status, review results, summary statements, and Notices of Award
- Other Commons features (e.g., Just In Time, eSNAP, Closeout, Financial Status Report) for previously submitted applications/awards

Search by Grants.gov Tracking Num

Enter the Grants.gov Tracking Number into the following box for easy access to a specific award application

Tracking Number Search

- The resulting hitlist will have a **Human Subjects** button in the **Available Actions** column on those applications with Inclusion Enrollment Reports (IERs). IERs replace the Inclusion Data Records (IDRs) used in the prior inclusion management system. Selecting the **Human Subjects** button will open the *Summary* page for that application with

the *HSCT Post Submission* tab available to access the human subjects data.

Home Admin Institution Profile Personal Profile Status ASSIST Prior Approval RPPR Internet Assisted Review xTrain xTRACT Admin Supp eRA Partners Non-Research

Notes & Tips:

- Important: The NIH provides the JIT (Just in Time) link in the Commons for scored applications. Please await instructions from the NIH on whether to complete this information

The following list of applications/grants represents a result of the search by Grants.gov Tracking # or a complete list of all your applications/grants. If you do not see a complete list of your applications/grants, please click List of Applications/Grants menu tab again.

Status Result - List of Applications/Awards 22

Grouped View Flat View

Application/Award ID	Grants.gov Tracking#	Proposal Title	PD/PI Name	eSubmission Status	Current Application Status	Status Date	Available Actions
5R03CA123456-02		Implementation Evaluation of a Cervical Cancer Screening Initiative	LUQUE, JOHN (PI)	Awarded, Non-fellowships only	08/19/2014	Closed RPPR Human Subjects	
11R03CA123123-01	GRANT00001234	Implementation Evaluation of a Cervical Cancer Screening Initiative	Luc, Jean S (PI)	Submission Complete	Awarded, Non-fellowships only	09/18/2012	JIT (times revised:2) Human Subjects

R03CA123456 2 09/18/2012 - 12/29/2015 (Project Period) Luc, Jean S (PD/PI) Implementation Evaluation of a Cervical Cancer Screening (Title) Awarded, Non-fellowships only

R21CA000123 1 12/01/2017 - 11/30/2019 (Project Period) Luc, Jean S (PD/PI) Cervical Cancer in Peruvia (Title) Not Discussed

Access via RPPR

To Access HSS via an RPPR, select the *RPPR* tab and then, in the *Edit* view, select the tab labeled, *G Special Reporting Req*.

Home Admin Institution Profile Personal Profile Status ASSIST Prior Approval RPPR xTrain xTRACT

Grant List Manage RPPR

A Cover Page B Accomplishments C Products D Participants E Impact F Changes G Special Reporting Req H Budget

G. Special Reporting Requirements ?

After selecting the *G Special Reporting Req* tab, scroll down to section *G.4.b Inclusion Enrollment Data* and then select the link for *Human Subjects*.

G.4 Human Subjects

G.4.a Does the project involve human subjects? ☒ Yes ☐ No

Is the research exempt from Federal regulations? ☐ Yes ☒ No
If yes, check appropriate exemption number(s).
☐ E1 ☐ E2 ☐ E3 ☐ E4 ☐ E5 ☐ E6

Does this project involve a clinical trial? ☒ Yes ☐ No
If yes, is this an NIH-defined Phase III Clinical Trial? ☐ Yes ☒ No

G.4.b Inclusion Enrollment Data

Please review the box below to determine if this project meets the definition of clinical research and requires the reporting of cumulative enrollment of subjects and the distribution of sex/gender, ethnicity and race. [Click here](#) for complete instructions about this requirement.

Inclusion Enrollment Report

Please click on the link below to view and update inclusion data records associated with this award.

[Human Subjects](#)

G.4.c ClinicalTrials.gov

The above methods will take the user to the *Application Information* screen and provide access to the *HSCT Post Submission* tab.

Click on the *HSCT Post Submission* tab. This will take you to a *Study Record(s)* screen where all study records and delayed onset studies associated with your grant are displayed.

Home > Search for Applications > Application Information

Hide Navigation Show Help

Application Information

Summary **HSCT Post Submission**

Application Information

Grant Number:	R01HG123456
Application Identifier:	99999 (Post Award Action)
Application Project Title:	Design and analysis of human gene mapping studies
PD/PI Name:	Humperdink, Budge
Organization:	UNIVERSAL UNIVERSITY
Project Period:	04/01/2018 - 03/31/2023
Status:	Work in Progress Submit
Status Date:	2018-05-21 12:23:24.000 PM EDT

3.1 Crosswalk Between IMS & HSS

There are differences in the way that inclusion data was accessed and managed in the retired IMS module compared to HSS. Please see this handy resource to figure out the differences.

[Crosswalk between the Inclusion Management System and HSS](#) - Word; May 16, 2018

4.1 Editing Studies

In order to edit study information, the Principle Investigators (PIs) or Signing Officials (SOs) can access the HSCT form using the *Human Subjects* links in either the RPPR or through the *Status* screen in eRA Commons. Refer to [Access Human Subjects System \(HSS\)](#) for details.

4.1.1 Human subjects information may need to be updated in the following scenarios:

- Post-award for updates to the *Research Performance Progress Report (RPPR)*
- Pre-award (post review) for *Just-in-Time (JIT)* information or correction of human subjects data
- Off-cycle updates as required in the *Funding Opportunity Announcement (FOA)* or terms and conditions of award

4.1.2 To edit an existing study, log into eRA Commons and access the Human Subjects link via the RPPR or Status tabs.

The *Application Information* screen is displayed, showing a summary of your grant. You have two ways of accessing and editing the study data. Both begin by accessing the *HSCT Post Submission* tab.

Click on the *Human Subjects Post Submission* tab. This will take you to a *Study Record(s)* screen where all study records and delayed onset studies associated with your grant are displayed.

Actions ?

VALIDATE

VIEW STATUS HISTORY

UPDATE SUBMISSION STATUS

Home > Search for Applications > Application Information

Hide NavigationShow Help

Application Information ?

SummaryHSCT Post Submission

Application Information

Grant Number:R01HG123456

Application Identifier:99999 (Post Award Action)

Application Project Title:Design and analysis of human gene mapping studies

PD/PI Name:Humperdink, Budge

Organization:UNIVERSAL UNIVERSITY

Project Period:04/01/2018 - 03/31/2023

Status:Work in ProgressSubmit

Status Date:2018-05-21 12:23:24.000 PM EDT

4.0.0.1 Option 1

- Click on the **View** button to open the study record data.



Summary HSCT Post Submission

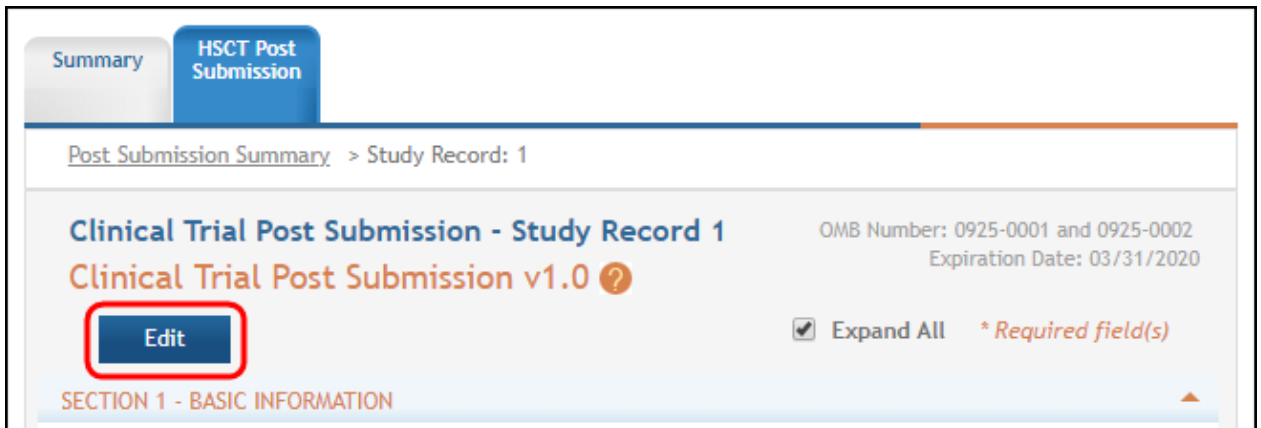
Clinical Trial Post Submission
Clinical Trial Post Submission v1.0 ?

Edit

Study Record(s) Showing 1 - 1 of total 1

Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
123456	Differentiation Therapy for GNAQ Mutated Uveal Melanoma	Yes	ReceivedByAgency	02/14/2019	View Export XML

- To update the human subjects information on that study, including inclusion enrollment data, click the **Edit** button at the top of the screen.



Summary HSCT Post Submission

Post Submission Summary > Study Record: 1

Clinical Trial Post Submission - Study Record 1 OMB Number: 0925-0001 and 0925-0002
Clinical Trial Post Submission v1.0 ? Expiration Date: 03/31/2020

Edit Expand All * Required field(s)

SECTION 1 - BASIC INFORMATION

- The study record will be opened and the fields may be updated.

The screenshot shows the 'Clinical Trial Post Submission - Study Record 1' form. At the top, there are two tabs: 'Summary' and 'HSCT Post Submission', with the latter being selected. Below the tabs, the breadcrumb 'Post Submission Summary > Study Record: 1' is visible. The main heading is 'Clinical Trial Post Submission - Study Record 1' with a version indicator 'Clinical Trial Post Submission v1.0' and a help icon. To the right, the OMB Number (0925-0001 and 0925-0002) and Expiration Date (03/31/2020) are displayed. An 'Edit' button is located below the heading. To the right of the button is a checked 'Expand All' checkbox and a note '* Required field(s)'. Below this is 'SECTION 1 - BASIC INFORMATION'. The first field is '1.1. Study Title (each study title must be unique)' with a text input containing 'Differentiation Therapy for GNAQ Mutated Uveal Melanoma'. The second field is '1.2. Is this Study Exempt from Federal Regulations?' with radio buttons for 'Yes' and 'No', where 'No' is selected. The third field is '1.3. Exemption Number' with a row of checkboxes numbered 1 through 8, none of which are selected.

4.0.0.2 Option 2

- Select the *HSCT Post Submission* tab and then click on the **Edit** button. (click to view)

This screenshot is similar to the previous one but includes red annotations. A red box highlights the 'HSCT Post Submission' tab, and another red box highlights the 'Edit' button. A red arrow points from the 'HSCT Post Submission' tab to the 'Edit' button, indicating the sequence of actions.

- Now you will see that the existing study has an **Edit** button available and there are additional buttons to add regular or delayed onset studies.

Summary

HSCT Post Submission

Clinical Trial Post Submission

Clinical Trial Post Submission v1.0 ?

Edit

Study Record(s)

Add New Study

 Showing 1 - 1 of total 1

Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
123123	Research Consortium of HPV-related Cervical Cancer	Yes	WorkInProgress	03/29/2018	<div>Edit</div> <div>View</div>

Delayed Onset Study(ies)

Add New Delayed Onset Study

Study ID	Study Title	Anticipated Clinical Trial?	Justification	Last Submission Date	Delete on save	Add/Update Attachment	View Attachment	Action
Nothing found to display								

Associated Studies Reported on Other Projects

Study ID	Study Title	Clinical Trial?	Last Submission Date	Reporting Project	Action
Nothing found to display					

Save and Keep Lock

Save and Release Lock

Cancel and Release Lock

- Select the **Edit** button for the existing study to open the edit screen.

Summary HSCT Post Submission

Post Submission Summary > Study Record: 1

Clinical Trial Post Submission - Study Record 1 OMB Number: 0925-0001 and 0925-0002
Clinical Trial Post Submission v1.0 ? Expiration Date: 03/31/2020

Edit Expand All * Required field(s)

SECTION 1 - BASIC INFORMATION

* 1.1. Study Title (each study title must be unique) Differentiation Therapy for GNAQ Mutated Uveal Melanoma

* 1.2. Is this Study Exempt from Federal Regulations? ☐ Yes ☒ No

1.3. Exemption Number ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

IMPORTANT: If the initial competitive segment was submitted on or after January 25, 2018 (i.e. a Forms E application) without a ClinicalTrials.gov Identifier (an NCT number), enter the appropriate NCT number in the field numbered 1.5. Select the Populate button and the system will do a best effort copy of form data from the official Clinical Trials records.

SECTION 1 - BASIC INFORMATION

* 1.1. Study Title (each study title must be unique)

TEST for Documentation 1

* 1.2. Is this Study Exempt from Federal Regulations?

☐ Yes ☒ No

1.3. Exemption Number

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

* 1.4. Clinical Trial Questionnaire

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants?

☒ Yes ☐ No

1.4.b. Are the participants prospectively assigned to an intervention?

☒ Yes ☐ No

1.4.c. Is the study designed to evaluate the effect of the intervention on the participants?

☒ Yes ☐ No

1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?


☒ Yes ☐ No

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable

Click the Populate button to retrieve data from ClinicalTrials.gov registration once Identifier is entered.

NCT12345678

Populate



4.1.3 Inclusion Enrollment Report

Standalone PHS Inclusion Enrollment Report forms are no longer used. Instead, data collection for up to 20 *Inclusion Enrollment Reports* has been folded into each *Study Record*. Click on the link in *Section 2* of the *Study Record* screen to initiate the *Inclusion Enrollment Report*.

SECTION 2 - STUDY POPULATION CHARACTERISTICS

2.1. Conditions or Focus of Study

Action

Nothing found to display

Add New Condition

2.2. Eligibility Criteria

Enter up to 15000 characters

Characters Remaining: 15000

2.3. Age Limits

Minimum Age

Maximum Age

2.4. Inclusion of Women, Minorities, and Children

Add Attachment

Delete Attachment

View Attachment

2.5. Recruitment and Retention Plan

Add Attachment

Delete Attachment

View Attachment

2.6. Recruitment Status

2.7. Study Timeline

Add Attachment

Delete Attachment

View Attachment

2.8. Enrollment of First Subject

Inclusion Enrollment Report(s)

Add New Inclusion Enrollment Report

Entry #	Enrollment Location Type	Enrollment Location	Action
Nothing found to display.			

For each *Inclusion Enrollment Report*, applicants will need to indicate whether an existing dataset or resource will be used and whether the enrollment location type is domestic or foreign.

There are also a few optional fields in the report, including a text entry *Comments* section.

SummaryR&R CoverCover Page SupplementOther Project InformationSitesSr/Key Person ProfileR&R BudgetResearch PlanHuman Subjects and Clinical Trials

Human Subjects Summary > Study Record: 1 > Inclusion Enrollment Report: 1

Inclusion Enrollment Report 1

PHS Human Subjects and Clinical Trials Information ?

Edit

* 1. Using an Existing Dataset or Resource

☐ Yes ☐ No

* 2. Enrollment Location Type

☐ Domestic ☐ Foreign

3. Enrollment Country(ies)

None selected ▾

4. Enrollment Location(s)

Enter up to 255 characters

Characters Remaining: 255

5. Comments

Enter up to 500 characters

Characters Remaining: 500

Planned and *Cumulative* enrollment data collection has been separated into separate tables.

Planned

	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Asian	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Native Hawaiian or Other Pacific Islander	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Black or African American	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
White	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
More than One Race	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Total	0	0	0	0	0

Cumulative (Actual)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/Alaska Native	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Asian	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Native Hawaiian or Other Pacific Islander	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Black or African American	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
White	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
More than One Race	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Unknown or Not Reported	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>
Total	0	0	0	0	0	0	0	0	0	0

Save and Keep Lock
Save and Release Lock
Save and Add
Cancel and Release Lock
Remove Report

4.1.4 Editing Inclusion Counts

Inclusion data is found at the end of Section 2.

SECTION 2 - STUDY POPULATION CHARACTERISTICS

2.1. Conditions or Focus of Study

Nothing found to display

Add New Condition

2.2. Eligibility Criteria

Enter up to 15000 characters

Characters Remaining: 15000

2.3. Age Limits

Minimum Age

0

Minutes

Maximum Age

N/A (No limit)

2.4. Inclusion of Women, Minorities, and Children

ASSIST_CT_InclnWmi

Replace Attachment

Delete Attachment

View Attachment

2.5. Recruitment and Retention Plan

ASSIST_CT_RecruRet

Replace Attachment

Delete Attachment

View Attachment

2.6. Recruitment Status

Recruiting

2.7. Study Timeline

ASSIST_CT_StdyTmlr

Replace Attachment

Delete Attachment

View Attachment

Inclusion Enrollment Report(s)

Add New Inclusion Enrollment Report

Entry #	Enrollment Location Type	Enrollment Location	Action
123123	Domestic	test location	<div>Edit</div> <div>View</div>

There are two ways to edit the existing Inclusion Enrollment Report (IER) data for Cumulative (Actual) counts:

1. You can update the cells online in the existing report itself.
2. You can download a template for entering participant-level data by clicking on the **Download Participant Level Data Template** button. This will download a spreadsheet file in the proper CSV format to be used by the system.

NOTE:

- If you plan to upload the data, you **must** use the template by selecting the **Download Participant Level Data Template** button. This will be a CSV file that can be updated with new totals.
-

- Individual-level participant data on sex/gender, race, ethnicity, and age at enrollment will be ***required*** in progress reports for competitive applications submitted for due dates on or after January 25, 2019 (see NIH Guide Notice NOT-OD-18-116).
-

4.0.0.3 To use the template:

- Download the spreadsheet template for entering participant -level data by clicking on the **Download Participant Level Data Template** button. Fill the template with data for the study.
 - The columns in the template ***should not be altered***; altering the format or category titles will result in an error during the uploading process.
 - Data may be copied/transferred into the template from another source or entered directly into the template.
- Once the new totals have been entered into the template and the file has been saved, use the **Upload Participant Level Data Attachment** button to upload the file which will update the Cumulative counts.

If you need to clear the current records, use the **Remove Current Participant Level Data** button.

Cumulative (Actual)

	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
Racial Categories	Female	Male	Unknown /Not Reported	Female	Male	Unknown /Not Reported	Female	Male	Unknown /Not Reported	
American Indian/Alaska Native	42	31	0	7	6	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	676	510	0	15	20	0	0	0	0	1221
White	3526	2663	0	300	214	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	240	0	0	0	0	240

Need Help ?
 Participant level data file (CSV):

Download Participant Level Data Template

Upload Participant Level Data Attachment

Download Current Participant Level Data
Remove Current Participant Level Data

Save and Keep Lock

Save and Release Lock

Save and Add

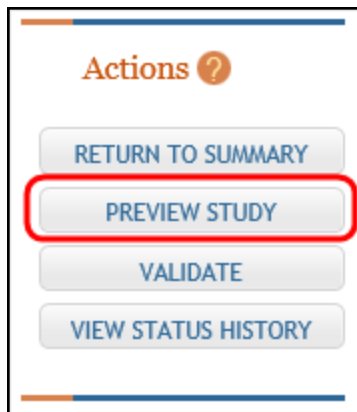
Cancel and Release Lock

Remove Report

For the Planned counts, the cells must be updated online in the report itself.

Planned					
	Ethnic Categories				
	Not Hispanic or Latino		Hispanic or Latino		Total
Racial Categories	Female	Male	Female	Male	
American Indian/Alaska Native	42	31	7	6	0
Asian	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0
Black or African American	676	510	15	10	1211
White	3526	2663	300	214	0
More than One Race	0	0	0	0	0
Total	0	0	0	230	230

The entire study can be previewed before submission by clicking on the **Preview Study** button on the left navigational column under Actions.



4.1.5 PI and SO Actions

If the PI is making changes:

- The PI can click the **Save and Release Lock** button to save the changes.
- The submission status changes to *Work in Progress*.
- PI changes status to *Ready for Submission*.

- SO logs into ASSIST, finds the application, and submits it.

NOTE: If the SO has delegated Submit authority to the contact PI, the PI may submit the application.

If the SO is making changes:

- The SO can click the **Save and Keep Lock** button to save the changes.
- The submission status remains in *Work in Progress*.
- The SO must click the **Save and Release Lock** button to allow the application to have the status changed.
- SO changes status to *Ready for Submission*.
- The *Submit* action becomes active on the *Application Information* page.
- SO clicks on the **Submit** button

NOTE: The SO can delegate Submit authority to the contact PI. If this delegation is not done, only the SO can submit the application to NIH. The submission sends all updated study records associated with the application to NIH at one time.

Program officials and grant specialists are notified automatically of study changes and can review those changes. Some changes may require prior approval.

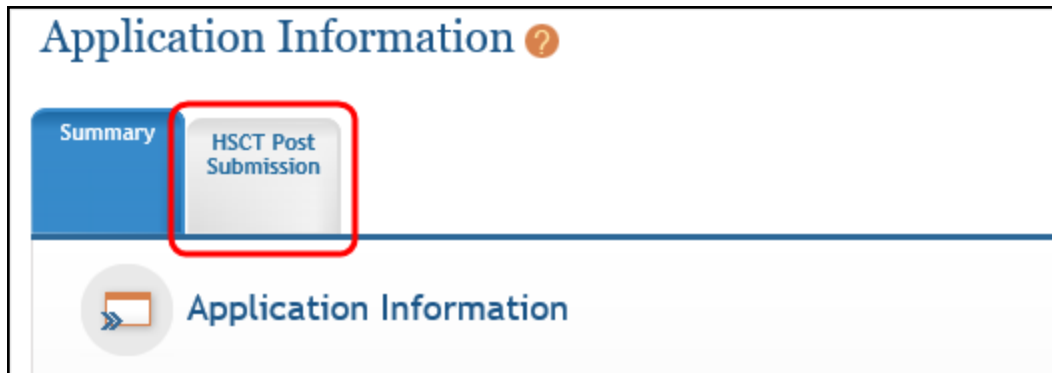
Tip: If the application has been submitted and needs to be placed back into a work in progress status, refer to these instructions to perform this action;

https://era.nih.gov/erahelp/ASSIST/default.htm#ASSIST_Help_Topics/5_Preview_Print_Submit/Revise_Application.htm?Highlight=status

5.1 Adding Studies

After the initial submission of the application, additional studies may be added once the summary statement is released.

Access the *HSCT Post Submission* tab via the *Human Subjects* links in the *Action* column of *Status* or the *Human Subjects* link in section G.4.b in the progress report.



Any study records already submitted will be displayed and may be viewed and buttons to **Add New Study** and **Add New Delayed Onset Study** will be displayed. Click on the appropriate button to add studies.

Clinical Trial Post Submission
Clinical Trial Post Submission v1.0 ?

Edit

Study Record(s) **Add New Study** Showing 1 - 1 of total 1

Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
123123	Research Consortium of HPV-related Cervical Cancer	Yes	WorkInProgress	03/29/2018	Edit View

Delayed Onset Study(ies) **Add New Delayed Onset Study**

Study ID	Study Title	Anticipated Clinical Trial?	Justification	Last Submission Date	Delete on save	Add/Update Attachment	View Attachment	Action
Nothing found to display								

Associated Studies Reported on Other Projects

Study ID	Study Title	Clinical Trial?	Last Submission Date	Reporting Project	Action
Nothing found to display					

Save and Keep Lock **Save and Release Lock** **Cancel and Release Lock**

Once the study has been added be sure to use the **Save and Keep Lock** or **Save and Release Lock** buttons to secure your updates.

5.1 How To Change the Application Status and Resubmit

5.1.1 To revise and resubmit an application:

1. From the *Application Information* page select the **Update Submission Status** button from the **Action** list on the left side of the screen.
The *Update Status* window displays.

2. Select the *Work in Progress* status from the **Select Status** drop-down list.

Update Submission Status

Select the new status

-- Select Status --

Work in Progress

Abandoned

Enter a comment on the submission

[or continue without adding a comment.](#)

Add comment Cancel

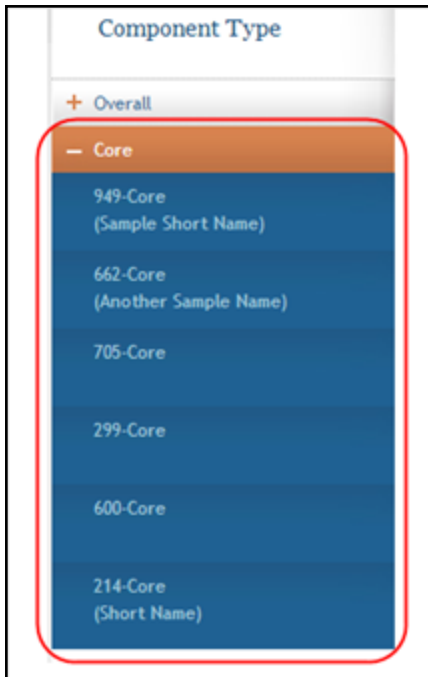
© 2018 NIH. All Rights Reserved.
Screen Rendered: 08/13/2018 02:34:41 EDT | Screen Id:
ASSIST0034@3692 Version: 2.30.00

3. Complete the status update:
 - a. Enter a comment in the provided text box.
 - b. Select the **Add comment** button.

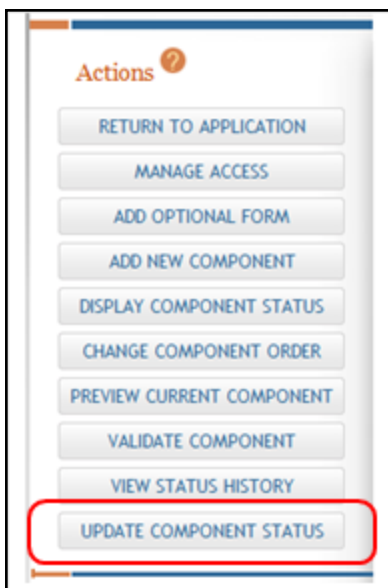
-OR-

 - c. Select the link titled **or continue without adding a comment** to update the status without entering a comment in the provided text box.

4. Select the component needing revision from the Component Type section of the page.



5. Select the Update Component Status button from the **Actions** section of the page.



6. Update the status of the component to *Work in Progress* by selecting it from the drop-down box, entering comments, and selecting the **Add Comment** button.

Once the status of the component is *Work in Progress*, the appropriate component form(s) can be updated. Navigate to the appropriate forms, make the changes, and re-submit the application. Refer to the help topic titled [Submit the Application](#) for information on submitting the application.

NOTE: Only the signing official (SO) or a delegated contact PI can submit the application to NIH.

6.1 Convert Delayed Onset to Full Study Record


6.1.1 Flow:

1. Click on the **Edit** Button
2. Click the **Convert** button – the system displays following warning:
 - a. Clicking “Convert” will change this record to a full study record and the study will no longer be considered delayed onset. The delayed onset justification will be removed. Are you sure you want to make this change?"
3. If you choose the **Cancel** option, you will stay on the *Post Submission* screen and the Delayed Onset remains as Delayed Onset
4. If you choose the **Continue** option you will be taken to the *Study Page* with title populated and rest of the fields empty.
5. Select **Save** (and keep or release lock) after completing the fields on the *Study Page*.
6. The action of saving the study removes the study from the *Delayed Onset Study* table and a new study is saved and added to the *Study Record* table.

Delayed Onset Study(ies) Add New Delayed Onset Study

Study ID	Study Title	Anticipated Clinical Trial?	Justification	Last Submission Date	Delete on save	Add/Update Attachment	View Attachment	Action
	Added new delayed on	<input checked="" type="radio"/> Yes <input type="radio"/> No	ASSIST_CT_DOnsetStudy12.pdf		<input type="checkbox"/>	Update	View	Convert

Notice:

 Clicking Convert will change this record to a full study record and the study will no longer be considered delayed onset. The delayed onset justification will be removed. Are you sure you want to make this change?

Continue Cancel

Study Record(s)					
Showing 1 - 4 of total 4					
Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
000001	Treatment of Older Adults with Hypertension: Study 1	No	WorkInProgress	04/28/2017	View
000002	Treatment of Older Adults with Hypertension: Study 1	No	WorkInProgress	04/28/2017	View
	Safety and Efficacy of BI-885 in Pediatric Subjects	Yes	WorkInProgress		View
	Converted study	Yes	WorkInProgress		View

7.1 Study Statuses

A status will be maintained for each study version. There will be two primary values used:

Received by Agency: any new study version will have this status. Studies that initially come in on initial submission will have this status, and any post-submission of the study will have this status.

Accepted: when an award occurs, any studies for which the awarded project is the primary project will have this status. The latest version will also be labeled with the relevant FY of the award.

NOTE: The Status of a study version on a contract application should always be set to "Accepted".

8.1 When Should I Access HSS via the Status Module?

HSS is used to view and maintain inclusion data associated with your grant(s) and can be accessed in one of two ways, both through the eRA Commons system: via the **Status** module –or– via the **RPPR Section G. Special Reporting Requirements**.

8.1.1 When to Use the Status Module Instead of RPPR

There are several reasons why you might need to access inclusion data through Commons Status rather than through your progress report. For example:

- Before award of a competitive application, changes may be necessary to the inclusion data submitted with the application via Grants.gov.
- Post-award, there may be a requirement to provide more frequent updates to inclusion enrollment in addition to any reporting associated with the RPPR.

Inclusion data cannot always be updated using Status. When application is undergoing peer review, the inclusion data is not accessible in the *Human Subjects System*. Also, after a grant is awarded, only the **View** links will be available for the IERs associated with fiscal year award. The data for a given fiscal year is locked when the award is issued and no further updates can be made. At that point, you can make updates via Status for the record associated with the next fiscal year.

For details on using the Status module for accessing HSS, please refer to [Access HSS](#). You can also access the HSS Online Help by selecting the help icons (?) on any of the HSS screens.

8.1 Roles & Privileges

8.1.1 HSS ROLES & PRIVILEGES:

Below are the roles and associated privileges pertinent to managing studies and projects in HSS.

	Principal Investigator	Signing Official
View study records	X	X
Receive notifications		X
Edit all HSCT and IER fields (except HS exemption and clinical trial code)	X	X
Initiate study record submission	X	X
Submit study record		X

8.1 Additional Resources (HSCT form and more)

HSS relies on information from more than one source and not all information provided in the HSS online help and PDF guides is exhaustive. Below are links to additional resources to provide

greater detail and explanation on the various topics and systems related to HSS.

- [HSCT form in ASSIST](#)
 - [Basic Information](#) (Study Record - Section 1)
 - [Study Population Characteristics](#) (Study Record - Section 2)
 - [Protection and Monitoring Plans](#) (Study Record - Section 3)
 - [Protocol Synopsis](#) (Study Record - Section 4)
 - [Other Clinical Trial-related Attachments](#) (Study Record - Section 5)
 - [Inclusion Enrollment Report](#)
 - [Participant Level Data Collection](#)
- [ASSIST \(online help\)](#) - HSS leverages ASSIST screens and therefore has the same look and feel.
- [HSS Training](#) - Contains links to user guide, video tutorials, IMS to HSS Crosswalk, and infographic of the HSS process
- [How to Apply - Application Guide](#) - Use application instructions, along with guidance in the funding opportunity announcement, to submit grant applications to NIH, CDC, FDA and AHRQ.